

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/841,730	LEE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Joseph T. Voitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to August 11, 2004.
2. ☒ The allowed claim(s) is/are 1-3,5,13,14,20 and 40-58.
3. ☒ The drawings filed on January 17, 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

- |                                                                                                                     |                                                                                                   |
|---------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)                                                    | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                       |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance              |
|                                                                                                                     | 9. <input type="checkbox"/> Other _____.                                                          |

Art Unit: 1632

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on August 11, 2004 has been entered.

**DETAILED ACTION**

This application filed April 24, 2001, is a continuation in part of 09/626,896, filed July 7, 2000, which is a continuation in part of 09/485,046, filed May 5, 2000, which a national stage filing of PCT/US98/15598, filed July 28, 1998, which claims benefit to US provisional application 60/054,461, filed August 1, 1997.

Applicants amendment filed August 11, 2004 has been received and entered. Claims 4, 6-12, 15-19 and 21-39 have been canceled. Claims 1, 2, 13, 14, 20, 40, 41 and 42 have been amended. Claims 47-58 have been added. Claims 1-3, 5, 13, 14, 20, 40-58 are pending and currently under examination.

***Election/Restriction***

Newly added claims 46-58 are drawn to the elected invention and therefore will be included in the instant examination. Applicant's election with traverse of Group I, in Paper No. 9

Art Unit: 1632

was acknowledged. Claims previously withdrawn to a non-elected invention have been canceled and no new arguments in traverse of the restriction requirement have been provided .

Claims 1-3, 5, 13, 14, 20, 40-58 are pending and currently under examination as they are drawn to a transgenic non-human mammal comprising a transgene encoding a truncated Activin Type II receptor.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Priority***

As noted previously, Examiner agrees that the instant application is fully supported by applications 09/626,896 and 09/485,046, however Examiner can not find similar support for the claimed invention in 60/054,461. Therefore, it is maintained that the instant application does not have priority to 60/054,461.

No new arguments have been provided by Applicants regarding the priority.

### ***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance:

As indicated in the previous office action, the claims are free of the art of record because the art fails to teach or make obvious a transgenic non human animal expressing a truncated

Art Unit: 1632

Activin Type II receptor wherein said non human animal exhibits increased muscle mass. Upon review of the art of record, it is clear that the expression of a Activin receptor without kinase activity, but maintaining its ability to bind other receptor partners, will result in a dominant negative protein. This is supported by naturally occurring mutations and in the artificial construct reduced to practice in the working examples of the instant specification. Moreover, based on the known function and structure of the RIIA and RIIB receptors, the art supports that each will share the same properties. Finally, given the evidence of record, both art and working examples that the function and affect of the Activin receptor is in the muscle cells, Examiner would concede that any muscle specific promoter that provides elevated levels of the Activin receptor in the muscle would likely result in the phenotype of increased muscle mass, as seen in the natural occurring mutant and the transgenic mouse reduced to practice in the instant application.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Application/Control Number: 09/841,730

Page 5

Art Unit: 1632

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

JOSEPH WOITACH  
PATENT EXAMINER

Joe Woitach  
AU1632